

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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|--|---|-------------------------------|
| IN RE PHARMACEUTICAL INDUSTRY                          | ) | MDL No. 1456                  |
| AVERAGE WHOLESAL PRICE LITIGATION                      | ) | Master File No. 01-12257-PBS  |
|  | ) | Subcategory Case No. 06-11337 |
|  | ) |                               |
|  | ) | Judge Patti B. Saris          |
| THIS DOCUMENT RELATES TO:                              | ) |                               |
| State of California, ex rel. Ven-A-Care of the Florida | ) | Magistrate Judge              |
| Keys, Inc. v. Abbott Laboratories, Inc., et al.        | ) | Marianne B. Bowler            |
| Case No: 1:03-cv-11226-PBS                             | ) |                               |
|  | ) |                               |

**DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S  
INDIVIDUAL LOCAL RULE 56.1 STATEMENT IN OPPOSITION TO  
PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF  
UNDISPUTED MATERIAL FACTS AS TO THE MYLAN DEFENDANTS**

Pursuant to Local Rule 56.1, Defendants Mylan Inc. (formerly known as Mylan Laboratories Inc.) and Mylan Pharmaceuticals Inc. (collectively, “Mylan”) submit the following Rule 56.1 Statement in opposition to Plaintiffs’ Local Rule 56.1 Statement of Undisputed Material Facts as to Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (“CA-Mylan-SOF”).

## **I. GENERAL RESPONSES AND OBJECTIONS**

Mylan generally objects to the CA-Mylan-SOF on the grounds that the unnumbered headings misstate, misconstrue and/or mischaracterize the underlying alleged “undisputed” facts they purport to introduce. Mylan further objects to the CA-Mylan-SOF in that these unnumbered headings lack adequate foundation. *See* Fed. R. Evid. 602. Accordingly, Mylan omits these improper and argumentative headings in its Specific Responses to the CA-Mylan-SOF below. In addition, Mylan generally objects to the CA-Mylan-SOF insofar as it inappropriately conjoins completely unrelated or marginally related statements together as one

purported factual statement. Mylan generally objects to the CA-Mylan-SOF insofar as it does not specifically relate to the Mylan drugs at issue on this motion. Mylan generally objects to the CA-Mylan-SOF insofar as it is immaterial to the issues before the Court on the present motion. Mylan generally objects to the citation of evidence which does not support a particular fact or is not the best evidence of a particular fact. Mylan's agreement that a fact is undisputed is not an agreement that Plaintiffs' citations support such fact. Mylan generally objects to the CA-Mylan-SOF on the grounds that Mylan Inc. is a holding company and does not manufacture, market or sell any pharmaceuticals. (*See* Palermo Decl., Ex. A at 10:9-11:21, 12:20-21; Palermo Decl., Ex. B at 70:9-71:18.)

## **II. SPECIFIC RESPONSES TO PLAINTIFFS' STATEMENT OF ALLEGED FACTS**

1. During the period from 1994 through 2004, pharmacies and other Medi-Cal providers routinely submitted pharmaceutical claims to Medi-Cal (through its fiscal intermediary, EDS) for reimbursement of the Mylan drugs at issue in this action (the "Subject Drugs") that those providers had dispensed to program beneficiaries. (Declaration of Nicholas N. Paul in Support of Motion for Partial Summary Judgment (hereinafter, "Paul") Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

### **RESPONSE:**

Mylan does not dispute that providers submitted pharmaceutical claims to Medi-Cal for reimbursement of drugs those providers had dispensed to program beneficiaries. Mylan further states that the reimbursement claims contained the providers usual and customary charge to the general public. (Palermo Decl. Ex. C at 689:5 to 692:10.) Mylan however disputes CA-Mylan-SOF ¶ 1 on the grounds that the declaration of J. Kevin Gorospe refers generally to all defendants in this action and all the Subject Drugs and does not refer specifically to Mylan or Mylan's drugs.

2. Medi-Cal paid those claims (through EDS) with Government funds. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

### **RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 2 on the grounds that the term “Government funds” is vague, ambiguous, and undefined. Mylan further states that, throughout the relevant time period, at least 50% of each claim at issue was paid with funds provided by the federal government. *See* 42 U.S.C.A. § 1396d(b) (2009). Mylan further states that the amounts paid by Medi-Cal for the Subject Drugs have been further offset by rebate payments made by Mylan to California pursuant to federal law. *See* 42 U.S.C. § 1396r-8.

3. Pursuant to applicable statutory and regulatory requirements, the claims were adjudicated and paid *at the lesser of* the provider’s usual and customary charge or at the Cost of the Drug Product plus a dispensing fee. By statute, the total payment was then reduced by an amount varying over time from \$.10 to \$.50 per claim. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5a, 5b, 6.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 3 on the grounds that the term “Cost of the Drug Product” is vague, ambiguous, and undefined. Mylan disputes CA-Mylan-SOF ¶ 3 on the grounds that California was never limited by law to paying the cost of a drug on a drug-by-drug basis. Rather, for drugs subject to a Federal Upper Limit (“FUL”), federal regulations merely limited payment in the aggregate, across all drugs, to the amount that would result from the application of the FUL plus a reasonable dispensing fee. (Robben Decl., Ex. 6.)<sup>1</sup> For all “other drugs” not subject to a FUL, a state agency’s payment “must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) Estimated Acquisition Cost (“EAC”) plus reasonable dispensing fees established by the agency or (2) providers’ usual and customary charges to the general public.” *See* 42 C.F.R. § 447.332(b) (2004). In comments adopting these regulations, HCFA explicitly noted payments for some drugs could exceed limits, provided that the limits were met in the aggregate:

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<sup>1</sup> “Robben Decl., Ex. \_\_\_” refers to the Declaration of Philip D. Robben in Support of Defendants’ Motions for Partial Summary Judgment and the exhibits annexed thereto, Dkt. Nos. 6702 to 6702-69.

# 1. Increased State Flexibility

\* \* \*

Under these final regulations, State agencies will be able to make higher payments for some listed drugs as long as they pay at rates lower than those listed for other drugs on the list. ... Similarly, State agencies may employ essentially the same approach in meeting the limits for all other drugs. That is, the same principal of balancing payment increases for some drugs with decreases for other drugs also applies in determining whether aggregate payments exceed the limit.

Fed. Reg. Vol. 52, No. 147, July 31, 1987, at pp. 28655.

Within these guidelines, California had broad discretion to set its reimbursement methodology as it saw fit (Robben Decl., Ex. 2 at 431:4-9; Robben Decl., Ex. 3 at HHC002-0565; Robben Decl., Ex. 4 at 433:8-449:12; Robben Decl., Ex. 5 at 209:11-210:15), subject only to the requirement that its payments were consistent with efficiency, economy, and access to quality care (*see* Joint SOF at ¶¶ 14, 52, 56, 57<sup>2</sup>; *see also* Robben Decl., Ex. 7 at 108:3-109:13; Robben Decl., Ex. 8 at 307:13-308:5; Robben Decl., Ex. 9 at 464:2-465:7; Robben Decl., Ex. 10 at 49:10-51:18.) Mylan further refers the Court to statutes and regulations governing California's reimbursement methodology as the best evidence of Medi-Cal's reimbursement methodology during the relevant time period.

4. The Cost of the Drug Product was set at *the lowest of* the drug's Estimated Acquisition Cost ("EAC"), the Federal Allowable Cost (FAC, a/k/a FUL), or (c) the Maximum Allowable Ingredient Cost (MAIC).<sup>3</sup> (Paul Ex. 1 (Gorospe Decl.), at ¶ 5a, 5b.)

## **RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 4 on the grounds that the term "Cost of the Drug Product" is vague, ambiguous, and undefined. Mylan does not dispute that, throughout the

<sup>2</sup> "Joint SOF at ¶ \_\_\_\_\_" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment, Dkt. No. 6703.

<sup>3</sup> There are no claims paid at MAIC at issue in this case.

relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the lower of EAC, the FUL, the Maximum Allowable Ingredient Cost (“MAIC”), or the charge submitted by the provider. (Joint SOF at ¶ 18; Robben Decl., Ex. 13.) Mylan further refers the Court to statutes and regulations governing California’s reimbursement methodology as the best evidence of Medi-Cal’s reimbursement methodology during the relevant time period.

Mylan disputes CA-Mylan-SOF ¶ 4 on the grounds that California never intended payments based on EAC, FUL, or MAIC to approximate providers’ actual cost for the drug product on a drug-by-drug basis. Mylan adopts herein its response to CA-Mylan-SOF ¶ 3 and further states that, consistent with the flexibility afforded by the federal regulations, California adopted reimbursement methodologies that it knew would pay providers more than their actual acquisition costs, particularly for generic drugs, for its own policy reasons. For instance, when it adopted the 1987 federal FUL regulations, California noted with approval that it would pay a “spread” of more than 100 percent for a generic drug and considered this a benefit for the Medi-Cal program, because it would promote the use of lower-cost generics. (Joint SOF at ¶ 26; Robben Decl., Ex. 17, Addendum at p.2, ¶ 5.) During the late 1990s and early 2000s, California considered multiple proposals to reduce its reimbursement payments to levels that would be closer to what providers paid to acquire drugs, but never adopted these proposals, citing concerns that the reduced payments would limit Medi-Cal beneficiaries’ access to care. (Joint SOF at ¶¶ 33, 35, 36; Robben Decl., Exs. 24, 25 at 147:19-158:18, 27-29.) When California did revise its reimbursement methodology, first in 2002 and again in 2004, it made only modest reductions to reimbursement payments and acknowledged that its payments for generic drugs still significantly exceeded providers’ acquisition costs. (Joint SOF at ¶¶ 51-59; Robben Decl., Exs. 35-39.)

5. The Estimated Acquisition Cost for the Subject Drugs was determined at all relevant times at the AWP's reported by First Data Bank ("FDB") less a discount of either 5% (from 1994 through October 2002), 10% (from November 2002 through August 2004), or 17% (August 2004 through December 2004). (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5b, 7.)

**RESPONSE:**

Mylan does not dispute that California used these formulas to calculate EAC for some reimbursement purposes but states that the underlying statutes and regulations are the best evidence of California's reimbursement methodology. Mylan further states that California's claims data is the best evidence of what criteria was actually used to determine reimbursement for claims paid based on EAC. Mylan further states that EAC would be used to calculate reimbursement only when the resulting payment would be lower than the usual and customary charge submitted by the provider. (Palermo Decl. Ex. C at 689:5-692:10.)

6. Throughout the relevant time period, Mylan set AWP's for its products and reported those prices to pricing compendia, including FDB. (Paul Ex. 2 (11/21/08 Eric Belldina Dep.), at 49:5-22; Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 38:22-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-137:11.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 6. Mylan does not dispute that it reports its AWP's to third party pricing compendia, such as First DataBank, RedBook and Medi-Span. (Palermo Decl., Ex. D at 28:19-29:02.) However, the AWP's published by third party pricing compendia, such as First DataBank, may not necessarily reflect the AWP's reported by Mylan. (Palermo Decl., Ex. D at 20:12-22:06; *see also* Palermo Decl., Ex. E at 68:6-19 ("[T]he number we send to First DataBank isn't necessarily the number that they will ultimately publish as the AWP.... [T]hey may end up publishing an AWP that is a different number than what we sent in.")) As Mylan's 30(b)(6) representative, David Workman, testified:

Q: Do you recall any particular event in which Mylan corrected the price that it had in its database in order to

reflect the price that was being published on its behalf by one of the pricing compendia?

- A. I don't recall specific instance but I know that we have in the past corrected our database to reflect what was published or what was discussed with a pricing publication.

(Palermo Decl., Ex. D at 22:08-16; *see also* Palermo Decl., Ex. E at 104:19-23, 108:12-16

("there are times when the number that gets published by these publishers isn't the same as the number that we sent them").) Patricia Kay Morgan testified that the prices reported by FDB are set in accordance with FDB's editorial policies, and that manufacturers do not control the prices that FDB ultimately reports as AWP. (Palermo Decl., Ex. X at 42:10-20, 158:7-13.)

7. Mylan set the AWP for its product without even attempting to have those numbers reflect market prices. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 38:22-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-139:18; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 7 on the grounds that it mischaracterizes the testimony of Hal Korman, Steve Krinke, and Brian Roman. None of these witnesses testified that Mylan did not attempt to have its AWP reflect market prices. Mr. Korman testified that the criteria Mylan used in setting AWP is that it must be at least 10% off the brand drug to be characterized as a generic by the pricing compendia. Mr. Roman testified that while Mylan generally did not sell Mylan's products to Mylan's customers at AWP, Mylan does not know what providers may ultimately purchase Mylan's drugs at downstream. Indeed, Mr. Roman responded as follows in another deposition:

- Q. Okay. Well, let's establish one thing based on your last answer. You do agree with me, sir, that the term "average wholesale price" is not the price at which Mylan has ever sold any drugs to its customers?

- A. I can't be categorical about it. We've been in business 45 years and we sell about 150 different drugs today. So I don't know whether Mylan has sold products at AWP to its customers. It's possible we have at some point. But as a general matter, AWP is not a price at which Mylan sells Mylan's products to Mylan's customers. It doesn't mean it's not a price at which our products are sold downstream. The pharmacy may charge AWP to its customer, for example.

(Palermo Decl., Ex. E at 50:06-19.) Mr. Krinke, in the excerpt cited by Plaintiffs, corroborated that Mylan does not know what prices are charged downstream:

- Q. Okay. You didn't go to Pricing and Contracts to see what was actually being charged from a wholesaler to a pharmacy to establish those new AWP prices, did you?
- A. I wouldn't know nor do I believe Pricing and Contracts would know what a wholesaler charges a pharmacy for the product.

(Paul Ex. 4 at 138:16-139:1.)

Mylan disputes CA-Mylan-SOF ¶ 7 on the grounds that Mylan did take into account various factors in the marketplace when it set its AWP, most notably, the AWP of its competitors. (Palermo Decl., Ex. K at 40:6-41:17, 84:16-85:2.) Mylan does not dispute that its AWP is generally a price that is set at the time of launch in reference to the equivalent brand product's AWP and any generic products' AWP where available. (Palermo Decl., Ex. E at 67:2-22; Palermo Decl., Ex. F at 130:16-132:18; Palermo Decl., Ex. G at 138:8-140:21; Palermo Decl., Ex. H at 64:8-16.) However, Mylan further states that it reports the AWP to various pricing compendia, such as First DataBank, in order to "get [Mylan's] drug classified by First DataBank as a generic drug eligible for substitution." (Palermo Decl., Ex. E at 67:02-22; Palermo Decl., Ex. I at 17:20-18:2.)

Mylan further states that, during the relevant time period, Mylan reported its WACs with its AWP to the pricing compendia. Mylan's WAC is and always has been a real



transaction price in the marketplace at the point of sale as it represents the price that the wholesaler is ultimately responsible for paying. (Palermo Decl., Ex. J at 103:03-24; 106:11-12); Palermo Decl., Ex. A at 230:20-233:16; Palermo Decl., Ex. G at 175:15-21, 181:09-182:11; Palermo Decl., Ex. H at 94:08-17.) Mylan's WAC is the invoice price for "all of [Mylan's] transactions with wholesalers," which comprises "a large part of Mylan Pharmaceuticals' business." (Palermo Decl., Ex. G at 175:10-21.) Mylan's WAC has real economic implications because it is directly tied to the amount Mylan must pay in discounts, rebates and chargebacks. (Palermo Decl., Ex. E at 69:2-70:16; Ex. J at 104:23-107:15.)

Mylan further disputes CA-Mylan-SOF ¶ 7 to the extent it implies that Mylan was obligated or required to report AWP that reflected fully discounted prices that pharmacies may ultimately pay wholesalers, or that California intended or expected AWP to reflect providers' costs. California has never defined AWP as anything other than a price listed in a compendia. (Joint SOF at ¶ 20.) Moreover, California has understood since at least the late 1970s that compendia AWP do not reflect prices generally paid in the marketplace and, in particular, that they significantly overstate providers' costs for generic drugs. (Joint SOF at ¶¶ 22-49.)

8. When it was the first company to market a particular generic product, Mylan generally set and reported as AWP for its products a price 10% below the AWP for the corresponding brand product. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 38:19-39:16.)

### **RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 8 on the grounds that it mischaracterizes the testimony of Hal Korman. Mr. Korman stated nothing about when Mylan "was the first company to market a particular generic product," but merely discussed the criteria that Mylan's AWP be at least 10% below the brand AWP to be classified as a generic.

Mylan adopts herein its response to CA-Mylan-SOF ¶ 7. The manner in which Mylan sets AWP varies “product to product,” based on a number of factors. (Palermo Decl. Ex. H at 64:8-16, 92:16-93:4.) Mylan does not dispute that its AWP is generally a price that is set at the time of launch in reference to the equivalent brand product’s AWP and any generic products’ AWP where available. (Palermo Decl., Ex. E at 67:2-67:22; Palermo Decl., Ex. F at 130:16-132:18; Palermo Decl., Ex. G at 138:8-140:21; Palermo Decl., Ex. H at 64:8-16, 92:16-93:4.) However, Mylan further states that it reports the AWP to various pricing compendia, such as First DataBank, in order to “get [Mylan’s] drug classified by First DataBank as a generic drug eligible for substitution.” (Palermo Decl., Ex. E at 67:02-22; Palermo Decl., Ex. I at 17:20-18:2.) Mylan’s AWP must be at least 10% to 11% below the branded AWP in order for Mylan’s products to be recognized as a generic. (Palermo Decl., Ex. G at 146:05–08.) Mylan’s practice of setting AWP in this manner “doesn’t mean it’s not a price at which [Mylan’s] products are sold downstream.” (Palermo Decl., Ex. E at 50:06-20.)

Mylan disputes CA-Mylan-SOF ¶ 8 to the extent it implies that Mylan considered its competitors’ AWP as part of its sales and marketing strategy. In instances where there are competing generics already in the marketplace, Mylan’s policy is to set its AWP in line with other generic competitors’ AWP, and not necessarily higher or lower. (Palermo Decl., Ex. F at 130:04-131:15; Palermo Decl., Ex. H at 64:8-16; Palermo Decl., Ex. G at 139:5-140:21; Palermo Decl., Ex. K at 79:17-80:9.) It is not Mylan’s practice or policy to set its AWP at the very minimum discount off brand AWP needed to ensure generic designation by pricing compendia. (Palermo Decl., Ex. G at 145:15-22.) Further, it is not Mylan’s policy to set the highest AWP possible in relation to the brand, as it may create the undesirable “perception [that Mylan’s] product is more expensive” to a potential customer. (Palermo Decl., Ex. F at 131:04-132:18.)

9. When Mylan launched a product and there was already a competitive generic product on the market, Mylan set its AWP by reference to the competitor's AWP. (Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 137:5-11; Paul Ex. 6 (10/15/08 David Workman Dep.), at 182:22-183:14.)

**RESPONSE:**

Mylan adopts herein its responses to CA-Mylan-SOF ¶¶ 7-8. Mylan disputes CA-Mylan-SOF ¶ 9 to the extent it implies that Mylan considered its competitors' AWP as part of its sales and marketing strategy. The manner in which Mylan sets AWP varies "product to product," based on a number of factors. (Palermo Decl. Ex. H at 64:8-16, 92:16-93:4.) In instances where there are competing generics already in the marketplace, Mylan's policy is to set its AWP in line with other generic competitors' AWP, and not necessarily higher or lower. (Palermo Decl., Ex. F at 131:04-132:18; Palermo Decl., Ex. H at 64:8-16; Palermo Decl., Ex. G at 139:5-140:21; Palermo Decl., Ex. K at 79:17-80:9.) It is not Mylan's practice or policy to set its AWP at the very minimum discount off brand AWP needed to ensure generic designation by pricing compendia. (Palermo Decl., Ex. G at 145:15-22.) Further, it is not Mylan's policy to set the highest AWP possible in relation to the brand, as it may create the undesirable "perception [that Mylan's] product is more expensive" to a potential customer. (Palermo Decl., Ex. F at 131:04-132:18.)

10. Mylan knew that the generic market was very competitive and that market prices for generic drugs tended to decline significantly after additional participants entered the market. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 153:19-154:21.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 10 on the grounds that it mischaracterizes the testimony of Hal Korman. Mr. Korman did not testify to the effect on generic drug prices upon the entry of additional market participants. He testified that the generic pharmaceutical market is generally "hypercompetitive" and that Mylan has "a large number of competitors from around

the world.” Mr. Korman also testified to Mylan’s declining profitability as a result of such intense competition: “the pricing on [Mylan’s] products is ever changing. In most cases, from a Mylan perspective of what Mylan makes, is those prices are declining and in – a downward trend.” (Paul Ex. 3, at 153:19-154:21.)

During the relevant time period, these declining prices were reflected in Mylan’s reported WACs and AMPs. Mylan’s WAC is and always has been a real transaction price in the marketplace at the point of sale as it represents the price that the wholesaler is ultimately responsible for paying. (Palermo Decl., Ex. J at 103:03-24; 106:11-12; Palermo Decl., Ex. A at 230:20-233:16; Palermo Decl., Ex. G at 175:15-21, 181:09-182:11; Palermo Decl., Ex. H at 94:08-17.) Mylan’s WAC is the invoice price for “all of [Mylan’s] transactions with wholesalers,” which comprises “a large part of Mylan Pharmaceuticals’ business.” (Palermo Decl., Ex. G at 175:10-21.) Mylan’s WAC has real economic implications because it is directly tied to the amount Mylan must pay in discounts, rebates and chargebacks. (Palermo Decl., Ex. E at 69:2-70:16; Palermo Decl., Ex. J at 104:23-107:15.)

Moreover, pursuant to the terms of the rebate agreement between Mylan Pharmaceuticals Inc. and the United States Secretary for Health and Human Services, which entered into the agreement on behalf of all states, including California, Mylan Pharmaceuticals Inc. has calculated and reported, on a quarterly basis, its net prices to wholesalers and distributors that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs. (Palermo Decl., Ex. L at § I(a); Palermo Decl., Ex. G at 66:09-72:13; Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23, 81:15-82:5.) AMP is defined under the rebate agreement as “the average unit price paid to the Manufacturer for the drug in the States by *wholesalers* for drugs distributed to the retail

pharmacy class of trade” and “includes cash discounts allowed and all other price reductions ... which reduce the actual price paid.” (Palermo Decl., Ex. L at § I(a) (emphasis added).)

11. Mylan generally did not change its reported AWP in response to changes in transaction prices for its complaint products. (Paul Ex. 7 (9/25/07 Steve Krinke Dep.), at 143:16-146:5; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 11 on the grounds that it mischaracterizes the testimony of Steve Krinke and Brian Roman. Mr. Krinke did not testify that Mylan did not change its AWP in response to changes in transaction prices, but merely described two reasons that “potentially could result” in a change to Mylan’s AWP, which were “that the product, in general, all competitors, had adjusted or moved to a point where Mylan was not similar to their product” and “if a database had reported Mylan as being a brand rather than a generic for that particular drug.” (Paul Ex. 7 at 144:21-146:5.) Mr. Roman’s testimony does not concern AWP reporting whatsoever but instead concerns whether Mylan generally sold its products to its customers at AWP.

Mylan disputes any implication or inference that not changing reported AWP “in response to changes in transaction prices” was in any way improper, that Mylan had any obligation to update its AWP “in response to changes in transaction prices,” or that California expected published AWP to reflect prices currently paid in the marketplace for Mylan’s drugs. California has never defined AWP as anything other than a price listed in a compendia. (Joint SOF at ¶ 20.) Moreover, California has understood since at least the late 1970s that compendia AWP do not reflect prices generally paid in the marketplace and, in particular, significantly overstate providers’ costs for generic drugs. (Joint SOF at ¶¶ 22-49.)

At all times during the relevant time period, the market prices for Mylan’s drugs were reflected in the WACs Mylan regularly reported to the pricing compendia. Mylan’s WAC

is and always has been a real transaction price in the marketplace at the point of sale as it represents the price that the wholesaler is ultimately responsible for paying. (Palermo Decl., Ex. J at 103:03-24, 106:11-12; Palermo Decl., Ex. A at 230:20-233:16; Palermo Decl., Ex. G at 175:15-21, 181:09-182:11; Palermo Decl., Ex. H at 94:08-17.) Mylan's WAC is the invoice price for "all of [Mylan's] transactions with wholesalers," which comprises "a large part of Mylan Pharmaceuticals' business." (Palermo Decl., Ex. G at 175:10-21.)

Moreover, pursuant to the terms of the rebate agreement between Mylan Pharmaceuticals Inc. and the United States Secretary for Health and Human Services, which entered into the agreement on behalf of all states, including California, Mylan Pharmaceuticals Inc. has calculated and reported, on a quarterly basis, its net prices to wholesalers and distributors that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs. (Palermo Decl., Ex. L at § I(a); Palermo Decl., Ex. G at 66:09-72:13; Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23, 81:15-82:5.) AMP is defined under the rebate agreement as "the average unit price paid to the Manufacturer for the drug in the States by *wholesalers* for drugs distributed to the retail pharmacy class of trade" and "includes cash discounts allowed and all other price reductions ... which reduce the actual price paid." (Palermo Decl., Ex. L at § I(a) (emphasis added).) Neither the rebate agreement nor 42 U.S.C. § 1396 instruct drug manufacturers as to how AWP should be defined, calculated, or reported to third-party pricing compendia. (Palermo Decl., Ex. L; 42 U.S.C. § 1396 *et seq.*) Mylan has fully complied with the terms and conditions set forth in its rebate agreement, as well any legal requirements, standards and procedures of the Medicaid program applicable to participating drug manufacturers. (Palermo Decl., Ex. G at 66:09-72:13;

Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23, 81:15-82:5; Palermo Decl., Ex. H at 278:09-280:01; Palermo Decl., Ex. M at 157:07-158:12.)

12. On occasion, Mylan raised the AWP for a product. (Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 135:16-137:4; Paul Ex. 7 (9/25/07 Steve Krinke Dep.), at 143:16-146:5; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 91:9-92:5.) However, Mylan did not actually sell its product at AWP. (Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

**RESPONSE:**

Mylan does not dispute that it occasionally revised the AWP for certain drugs, among other reasons, so that its AWP would be consistent with the AWP for competing products or so that the product would continue to be classified as a generic in pricing compendia. (Paul Ex. 7 at 144:21-146:5.) Mylan's primary purpose in reporting a change in its AWP to the pricing compendia was "[t]o make the marketplace aware that the products were being marketed and were available for sale." (Palermo Decl., Ex. I at 17:15-18:2.)

Mylan disputes the second sentence of CA-Mylan-SOF ¶ 12 on the grounds that it mischaracterizes the testimony of Brian Roman. Mylan does not dispute that Mr. Roman testified that Mylan generally does not sell its products to customers at AWP. However, Mr. Roman further testified that he could not categorically conclude that Mylan had never done so. (Paul Ex. 5 at 129:2-12.) In fact, Mr. Roman has also testified that Mylan's products may be sold at AWP downstream by providers:

- Q. Okay. Well, let's establish one thing based on your last answer. You do agree with me, sir, that the term "average wholesale price" is not the price at which Mylan has ever sold any drugs to its customers?

MR. ESCOBAR: Objection to the form.

- A. I can't be categorical about it. We've been in business 45 years and we sell about 150 different drugs today. So I don't know whether Mylan has sold products at AWP to its customers. It's possible we have at some point. But as a

general matter, AWP is not a price at which Mylan sells Mylan's products to Mylan's customers. It doesn't mean it's not a price at which our products are sold downstream. The pharmacy may charge AWP to its customer, for example.

(Palermo Decl., Ex. E at 50:06-19.)

13. Mylan was aware that it was necessary to report AWP's to the pricing compendia in order for its products to be reimbursed by third party payers, such as Medi-Cal. (Paul Ex. 9 (10/30/08 Robert Cunard Dep.), at 196:20-197:6; Paul Ex. 2 (11/21/08 Eric Belldina Dep.), at 161:15-23; Paul Ex. 7 (9/25/07 Steve Krinke Dep.), at 87:11-88:1; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 89:1-7, 241:3-15.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 13. As Brian Roman, Mylan's 30(b)(6) designee, explained, Mylan reports the AWP to various pricing compendia, such as First DataBank, in order to "get [Mylan's] drug classified by First DataBank as a generic drug eligible for substitution." (Palermo Decl., Ex. E at 67:02-22; Palermo Decl., Ex. I at 17:15-18:2 (Mylan's primary purpose for reporting AWP's to the pricing compendia was "[t]o make the marketplace aware that the products were being marketed and were available for sale").) Moreover, as Hal Korman, Mylan's 30(b)(6) designee, testified, reimbursement to providers was not a factor, much less a primary factor, motivating Mylan's decision to report AWP's to pricing compendia:

Q: Was one of Mylan's purposes in reporting these prices to First Data Bank so that these prices could be used by others for reimbursement purposes?

A: No.

(Palermo Decl., Ex. I at 17:15-19; *see also* Palermo Decl., Ex. G at 123:02-05 (Mylan's primary purpose for reporting AWP to First DataBank was "so that the trades and the industry would know we had a generic version available, and it was being sold at a discount to brand.").)



Mylan receives Medicaid rebate invoices from the states on a quarterly basis but does not keep track of the percentage of its total sales that are attributable to Medicaid. (Palermo Decl., Ex. E at 26:14-27:10; *see also* Palermo Decl., Ex. G at 194:02-15.) California has failed to adduce any evidence that Mylan was aware that “the majority of brand and generic” drugs sold by Mylan (or other manufacturers generally) were “covered by third-party reimbursement.” Indeed, when Mylan’s 30(b)(6) witness, Brian Roman, in preparation for his 30(b)(6) deposition asked Mr. Krinke whether the “Medicaid program was a major source of reimbursement for pharmaceuticals,” Mr. Krinke only recalled reading in a trade press “some figures like *ten or eleven percent* on an industry wide basis.” (Palermo Decl., Ex. E at 194:02-17 (emphasis added).)

Present and former employees of Mylan have consistently testified that it has not been Mylan’s practice or policy to consider reimbursement payments to providers when setting or reporting AWP for its products. (Palermo Decl., Ex. I at 17:15-18:13; Palermo Decl., Ex. G at 181:03-22.) It has not been Mylan’s practice or policy to attempt to ensure or maximize Medicaid reimbursement payments to pharmacies when selling or marketing its products to customers. (Palermo Decl., Ex. E at 28:12-29:10; Palermo Decl., Ex. N at 238:13-239:03.) Mylan has not received any part of the reimbursement amount paid by Medicaid. (*See* Palermo Decl., Ex. H at 272:9-15.) The primary focus of Mylan’s sales and marketing efforts is not aimed “at the back end of reimbursement” but rather is designed to “make sure our customers can get our product, that it’s not on back order, that we’re able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive.” (Palermo Decl., Ex. E at 28:12-29:10; *see also* Palermo Decl., Ex. O at TXMylan02893476.) Mr. Cunard, former VP of sales and marketing, testified:

Q. And what were the general basis (sic) on which you perceived that you competed with other companies with respect to the sale of pharmaceutical products?

A. As indicated earlier, price, supply, value-added services, CE programs

\* \* \*

A. Price, supply, value-added services such as continuing education programs, quality of product, reliability, reputation.

(Palermo Decl., Ex. H at 273:7-16.)

This is further corroborated by testimony of former sales personnel at Mylan Pharmaceuticals Inc., including Mr. Mauro, a national accounts manager during the relevant time period, who testified:

Q. Would you agree that part of your job as vice president for sales and as a director of the NAMs, the national account managers, and so forth over several years, part of your job was to try to convince customers how they can increase their profits when they buy and sell Mylan drugs?

MR. ESCOBAR: Objection to the form.

A. No, that was not something we did. The way we tried to promote our products to our customers were we were providing a broad offering of new items with a robust pipeline to keep them in service, and the company hasn't had a recall from a manufactured product in over 47 years.

(Palermo Decl., Ex. P at 278:4-18.) As Bob Potter, the Vice President of sales and marketing at Mylan Pharmaceuticals Inc. during the relevant time period, also stated:

Q. And reimbursement was never a concern in all those years when you were selling product to your customers?

A. It may have been a concern on their point, but our point is we go with our best price, and they make the decision if they'd like to buy our product or not. There's other products available in the hundreds of products that we do have.

I think if you go down to the key, also to influence sales, on this sheet, the most important ones that we haven't talked about is the value of our product, where we haven't had any recalls, and that is a very important piece of our whole [selling] process.

(Palermo Decl., Ex. Q at 77:12-78:3.)

14. FDB published the suggested AWP's reported by Mylan as the AWP's for Mylan's products. (Paul Ex. 10 (6/26/08 David Workman Dep.), at 35:12-18.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 14. Mylan reports its AWP's to third party pricing compendia, such as First DataBank, RedBook and Medi-Span. (Palermo Decl., Ex. D at 28:19-29:02.) However, the AWP's published by third party pricing compendia, such as First DataBank, may not necessarily reflect the AWP's reported by Mylan. (Palermo Decl., Ex. D at 21:08-22:06.) The price reporting services may either accept it, reject it or change it. (Palermo Decl., Ex. G at 141:08-13.)

As Mylan's 30(b)(6) representative, David Workman, testified:

- Q: Do you recall any particular event in which Mylan corrected the price that it had in its database in order to reflect the price that was being published on its behalf by one of the pricing compendia?
- A. I don't recall specific instance but I know that we have in the past corrected our database to reflect what was published or what was discussed with a pricing publication.

(Palermo Decl., Ex. D at 22:08-16; *see also* Palermo Decl., Ex. E at 104:19-23, 108:12-16

("there are times when the number that gets published by these publishers isn't the same as the number that we sent them").) Indeed, when asked whether the AWP's published by the pricing compendia for Mylan's products between 1997 and 2005 were all supplied by Mylan, without having independently verified the figures, Mr. Workman replied: "I believe they have and in the

review is comparison from consistency of either what we had sent or what they had published and correcting either based upon the basis of the conversations that were held between us and the publishing company.” (Paul Ex. 10 at 35:12-36:06.) Patricia Kay Morgan testified that the prices reported by FDB are set in accordance with FDB’s editorial policies, and that manufacturers do not control the prices that FDB ultimately reports as AWP’s. (Palermo Decl., Ex. X at 42:10-20, 158:7-13.)

15. Mylan maintained databases through which it regularly tracked the prices at which its products were being sold. (Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 224:8-225:8, 226:3-15, 227:7-11, 229:2-16; Paul Ex. 11 (11/20/08 David Workman Dep.), at 100:19-101:20, 128:2-19, 130:11-131:3, 157:6-23, 158:2-159:10.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 15. Mylan could not regularly track the prices at which all its products were being sold because Mylan has no visibility into the wholesale prices paid by pharmacies which do not have contracts with Mylan. (*See* Paul Ex. 3 at 37:22-38:5 (“Again, I – I don’t know that it is a [sic] average of a price that a retailer has paid. I don’t have that information of what every product was sold for.”); Paul Ex. 4 at 138:24-139:1 (“I wouldn’t know nor do I believe Pricing and Contracts would know what a wholesaler charges a pharmacy for the product.”).)

In the testimony cited by Plaintiffs, Brian Roman generally described Mylan’s various computer systems, on which the company tracks information such as contract prices with its customers, WAC prices, rebates, and chargebacks. (Paul Ex. 5 at 224:8-225:8, 226:3-15, 227:7-11, 229:2-16.) David Workman further explained the challenges of tracking the transactional prices for Mylan’s products net of all discounts, rebates or chargebacks that may be issued days, weeks, or months after the initial point of sale:

Q. Would you agree that as a general matter, Mylan and UDL have the capability of calculating net prices on their products from the actual sales transaction records?

A. Again, that's a difficult question to answer. There are some estimates, yes, but a lot of those – and you got to understand the timing too. A sales transaction is one thing, but at the end of the day, the net price may not be realized for several transactions dates, days, months, time that have past. So, yes, at the time of sale we will know what we have invoiced a customer at. If there are discounts that are then applied at a future date, we will not know that at that time, but not until after the fact that we receive that data.

(Paul Ex. 11 at 157:6-23.)

[REDACTED]

Moreover, pursuant to the terms of the rebate agreement between Mylan Pharmaceuticals Inc. and the United States Secretary for Health and Human Services, which entered into the agreement on behalf of all states, including California, Mylan Pharmaceuticals Inc. has calculated and reported, on a quarterly basis, its net prices to wholesalers and distributors that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs. (Palermo Decl., Ex. L at § I(a); Palermo Decl., Ex. G at 66:09-72:13; Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23, 81:15-82:5.) AMP is defined under the rebate agreement as “the average unit price paid to the Manufacturer for the drug in the States by *wholesalers* for drugs distributed to the retail pharmacy class of trade” and “includes cash discounts allowed and all other price reductions ... which reduce the actual price paid.” (Palermo Decl., Ex. L at § I(a) (emphasis added).) The AMP, by necessity, is a price that is computed later in time and after the initial sales transaction with the customer takes place, because the conditional discounts, rebates and chargebacks are not realized at the point of sale. (Palermo Decl., Ex. L at § I(a) (the AMP for a quarter “must be

adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized”).)

16. For internal business purposes, Mylan calculated accurate estimates of sales prices for its products on a regular basis. (Paul Ex. 11 (11/20/08 David Workman Dep.), at 157:6-23, 158:2-159:10.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 16 as immaterial on the grounds that California never required or expected Mylan to report any such prices to pricing compendia. Mylan further disputes CA-Mylan-SOF ¶ 16 on the grounds that it mischaracterizes the testimony of David Workman. Mr. Workman did not testify that Mylan calculated and tracked “accurate estimates of sales prices on a regular basis.” In fact, Mr. Workman was asked whether Mylan had the capability to calculate, on a bi-weekly basis, the potential net prices for its products by looking at actual sales records. (Paul Ex. 11 at 158:2-6.) He explained that, because of possible future discounts which may ultimately affect the net price, he could only *estimate* net prices at any given time:

- Q. I'll break it down then on time frame. Do you agree then on a bi-weekly basis, Mylan and UDL have the exact of calculating net prices for their products looking at their actual sales records?
- A. Again, I still think that's a difficult question. Let me give you an example. I can run a price list and apply all of the discounts that may hit that product by customer and say, if everything does happen, if we price this customer at this price point, this will happen; however, all of those discounts may not be applied at that time of sale. It may be something different in the future, and that won't be realized until after those transactions have been received or realized. So, yes, we can do some estimates, and for best price, for example, we do apply all of the discounts available; however, that still is an estimate.

(Paul Ex. 11 at 158:8-22.)

Moreover, pursuant to the terms of the rebate agreement between Mylan Pharmaceuticals Inc. and the United States Secretary for Health and Human Services, which entered into the agreement on behalf of all states, including California, Mylan Pharmaceuticals Inc. has calculated and reported, on a quarterly basis, its net prices to wholesalers and distributors that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs. (Palermo Decl., Ex. L at § I(a); Palermo Decl., Ex. G at 66:09-72:13; Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23, 81:15-82:5.) AMP is defined under the rebate agreement as “the average unit price paid to the Manufacturer for the drug in the States by *wholesalers* for drugs distributed to the retail pharmacy class of trade” and “includes cash discounts allowed and all other price reductions ... which reduce the actual price paid.” (Palermo Decl., Ex. L at § I(a) (emphasis added).) The AMP, by necessity, is a price that is computed later in time and after the initial sales transaction with the customer takes place, because the conditional discounts, rebates and chargebacks are not realized at the point of sale. (Palermo Decl., Ex. L at § I(a) (the AMP for a quarter “must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized”).)

17. Mylan contracted with large retail pharmacy chains for the sale of its products. (Paul Ex. 11 (11/20/08 David Workman Dep.), at 168:12-169:6; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 83:19-84:15.)

**RESPONSE:**

Mylan does not dispute that it contracted with large pharmacy retail chains but states that Mylan has other types of customers that do not dispense drugs to Medicaid beneficiaries or submit claims for reimbursement to state Medicaid programs, most notably pharmaceutical wholesalers. Palermo Decl., Ex. R at 100:2-16. Mylan further states that products sold to these other types of customers may ultimately be sold to pharmacies that do not

have contracts with Mylan and that Mylan has no visibility into the prices at which such pharmacies buy Mylan drugs. (*See* Paul Ex. 3 at 37:22-38:5 (“Again, I – I don’t know that it is a [sic] average of a price that a retailer has paid. I don’t have that information of what every product was sold for.”); Paul Ex. 4 at 138:24-139:1 (“I wouldn’t know nor do I believe Pricing and Contracts would know what a wholesaler charges a pharmacy for the product.”).)

18. Mylan did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products’ AWP’s or otherwise. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 37:6-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-139:18.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 18 on the grounds that California never required or expected Mylan to report “any average or compilation of [transactional prices]” to the pricing compendia or Medi-Cal. Mylan states that it has reported the fully discounted “transactional prices” to CMS and the various states, including Medi-Cal, in the form of AMPs or URAs. Indeed, Mylan Pharmaceuticals Inc. has entered into a rebate agreement with the Department of Health and Human Services and the various states pursuant to 42 U.S.C. § 1396r-8. (Palermo Decl., Ex. L.) Mylan Inc. has not entered into any rebate agreement. Mylan Inc. is a holding company and does not manufacture, market or sell any pharmaceuticals. (*See* Palermo Decl., Ex. A at 10:9-11:21, 12:20-21; Palermo Decl., Ex. B at 70:9-71:18.) Pursuant to the terms of Mylan Pharmaceuticals Inc.’s rebate agreement, to which the State of California is a party, Mylan Pharmaceuticals Inc. has calculated and reported, on a quarterly basis, its net prices to wholesalers and distributors that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs. (Palermo Decl., Ex. L at § I(a); Palermo Decl., Ex. G at 66:09-72:13; Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23; 81:15-82:5.) AMP is defined under the rebate agreement as “the average unit price paid to the



Manufacturer for the drug in the States by *wholesalers* for drugs distributed to the retail pharmacy class of trade” and “includes cash discounts allowed and all other price reductions ... which reduce the actual price paid.” (Palermo Decl., Ex. L at § I(a) (emphasis added).) The AMP, by necessity, is a price that is computed later in time and after the initial sales transaction with the customer takes place, because the conditional discounts, rebates and chargebacks are not realized at the point of sale. (Palermo Decl., Ex. L at § I(a) (the AMP for a quarter “must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized”).)

Mylan further states that at all times during the relevant time period, Mylan also reported its WACs to the pricing compendia. Mylan’s WAC is the invoice price to wholesalers and represents the price that is being charged to its wholesale customers at the time of sale. (Palermo Decl., Ex. J at 103:03-24, 106:11-12 (“we invoice wholesalers at WAC” and “[t]hey’re responsible for that invoice”); Palermo Decl., Ex. A at 230:20-233:16; Palermo Decl., Ex. G at 175:15-21, 181:09-182:11; Palermo Decl., Ex. H at 94:08-17 (“WAC is the invoice price and the price that wholesalers and distributors pay for the product”).) Mylan’s WAC is the invoice price for “all of [Mylan’s] transactions with wholesalers,” which comprises “a large part of Mylan Pharmaceuticals’ business.” (Palermo Decl., Ex. G at 175:10-21.)

Mylan’s WAC is set on a product-by-product basis in light of existing market conditions and the competitive environment. (Palermo Decl., Ex. K at 98:02-101:13; *see also* Palermo Decl., Ex. H at 92:16-93:4.) Much like any other business operating in a competitive industry, Mylan has looked at market intelligence and market forecasts as well as its own operating costs, in determining its prices such as WAC. (Palermo Decl., Ex. G at 300:9-301:12; Palermo Decl., Ex. M at 153:21-154:11.) Within the bounds of the law, Mylan has also obtained

pricing information directly from customers, which may also factor into Mylan's setting of its WAC. (Palermo Decl., Ex. E at 139:2-20 ("if a customer wants to tell us that they're buying a drug for a particular price, that could be a good source of information").) As part of this determination, Mylan has also looked at its competitors' WACs to gauge its competitors' price points for their products. (Palermo Decl., Ex. F at 69:21-70:09 (describing competitors' WAC as "part of the market information" that Mylan would consult when setting its WAC).) As Mr. Workman explained, Mylan may also look at competitors' other price points obtained through IMS material, wholesaler price lists that are publicly available, federal supply schedule ("FSS") and/or VA prices available from the US Department of Veterans Affairs website. (Palermo Decl., Ex. F at 62:06-63:08, 68:18-70:09.) On the other hand, Mylan has competed on price by charging its customers prices that are *lower than* its competitors' prices, including the WAC:

Q. And when you say the competitive conditions, what do you mean?

A. The factors of supply and demand, looking at who else is selling it, what prices exist in the marketplace; we're never – even though we may be the first generic, that there is an existing marketplace for this drug that has been created by the brand company that exists when we come into it; so, you know, a significant part of the philosophy, as I said, would be that we're offering all of our products as a discount to the brand as an alternative, as a lower price alternative for the same medicine; so the prices would be lower than the corresponding brand prices.

(Palermo Decl., Ex. G at 300:20-301:12; *see also* Palermo Decl., Ex. K at 98:02-101:13; Palermo Decl., Ex. H at 92:16-93:4, 275:03-277:03 ("[a]djustments to WAC that were done proactively would be more around a decrease because that would decrease our costs to the customer base and increase our profitability if we were able to achieve that"); Palermo Decl., Ex. N at 238:13-239:03 ("we just try to sell [pharmacies] the product at the price that they can live with and that we are happy with, and what happens after that is their responsibility").) To the extent Mylan

has negotiated contract prices with retail or indirect customers at the time of launch, Mylan would consider such prices in relation to Mylan's potential chargeback obligations, prompt pay discounts, as well as the manufacturer cost (material-labor-overhead) for the product as part of its overall determination of the WAC. (Palermo Decl., Ex. K at 98:02-104:13; Palermo Decl., Ex. G at 182:01-11.)

Mylan's WAC is and always has been a real transaction price in the marketplace at the point of sale as it represents the price that the wholesaler is ultimately responsible for paying:

- A. WAC is a real price, and wholesalers, their net prices were based upon that WAC price, but, over time, it evolved where they established their own contract and their own contract price, and that was for their source program, not their entire book of business.

(Palermo Decl., Ex. J at 107:09-15.) Mylan does not know at the point of sale which of the products shipped to the wholesaler at WAC is ultimately resold by the wholesaler or distributor to entities that have an indirect supply contract with Mylan or to entities that have a contract with the wholesaler under the wholesaler's own source program, such that Mylan's chargeback obligations would begin to accrue. (Palermo Decl., Ex. J at 108:19-109:09 ("it is not a transaction or invoice that is paid in a vacuum" but rather there "are many moving parts to that invoice"); Palermo Decl., Ex. J at 118:24-119:08 (a wholesaler may "be responsible for the full WAC, because we would not be receiving a chargeback either for a third party or for their source program.")).) Discounts, rebates, chargebacks and promotional allowances are conditional and not realized at the point of sale. (Palermo Decl., Ex. F at 110:01-113:11.) With respect to sales outside the wholesaler source program or entities without a pre-existing contract with Mylan, Mylan's WAC is and has been the price that wholesale customers pay Mylan with respect to

those sales, less any conditional discounts such as the 2% prompt pay or a full-line credit that the wholesale customer may earn:

- A. When they do sell a product out under their source program or under a third-party contract, at a designated negotiated contract price, a chargeback is processed, and a chargeback is the difference between WAC and that contract price. If they sell it to a pharmacy that is not a part of a third-party contract or not a part of their source program, we would not receive a chargeback for that, so they would be responsible for that invoice.

(Palermo Decl., Ex. J at 106:18-107:3.) The WAC is “not an average” but a price that is actually paid by wholesalers and thus “a price point that is representative of the wholesale acquisition cost.” (*See also* Palermo Decl., Ex. J at 103:13-104:10.)

Even in the context of sales to indirect customers, WAC represents a price with discernible economic impact since from “a financial perspective, we were concerned of our WAC prices and our prompt payment obligation and our chargeback obligation, compared to our contract prices” and thus Mylan will “analyze all of those components of price when making a [WAC] recommendation.” (Palermo Decl., Ex. K at 101:20-102:15.) In such instances, Mylan’s WAC has real economic implications because it is directly tied to the amount Mylan must pay in discounts, rebates and chargebacks. (Palermo Decl., Ex. E at 69:2-70:16; Palermo Decl., Ex. H at 275:03-277:03 (an “increase of WAC where there’s specific discounts tied to it around the wholesale programs would actually be counter-productive to the profitability of Mylan”).) As set forth above, Mylan’s WAC is consistent with the federal definition of WAC set forth in 42 U.S.C. § 1395w-3a, which states as follows:

The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is

available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 U.S.C. § 1395w-3a(c)(6)(B) (effective December 8, 2003).

As noted above, consistent with the federal definition of WAC, Mylan's WAC has not included and does not include the net effect of discounts, chargebacks, rebates, and other cost adjustments which cannot be determined until after (and sometimes years after) the date of original sale. (*See* Palermo Decl., Ex. E at 69:2-70:16; Palermo Decl., Ex. G at 176:12-177:7; Palermo Decl., Ex. H at 276:1-12.) Such discounts and rebates cannot be determined on the date of the invoice because by their very nature they can only be earned after the transaction is complete, including for example, prompt pay discounts which are based on speed of payment, and performance-based rebates based on volume purchasing over a period of time. (*See* Palermo Decl., Ex. H at 276:1-12.) Moreover, the rebate agreement evinces an understanding and expectation by the industry and the parties to the agreement that manufacturers would be issuing discounts, rebates, chargebacks and "other price reductions," which would be reflected in their AMPs but not in their WACs. (Palermo Decl., Ex. L at § I(a); *see also* 42 U.S.C. § 1396r-8.)

Mylan further disputes CA-Mylan-SOF ¶ 18 on the grounds that it mischaracterizes the testimony of Hal Korman and Steve Krinke. Both witnesses were asked whether, in setting new AWP prices, they considered the price a wholesaler actually charges a pharmacy for a drug. Both responded that they had no way of knowing the price a wholesaler actually charges a pharmacy for a drug and therefore did not use this information when setting AWP. (*See* Paul Ex. 3 at 37:22-38:5 ("Again, I – I don't know that it is a [sic] average of a price that a retailer has paid. I don't have that information of what every product was sold for."); Paul Ex. 4 at 138:24-139:1 ("I wouldn't know nor do I believe Pricing and Contracts would know what a wholesaler charges a pharmacy for the product.")) Plaintiffs mistakenly assume that,

because Mylan did not consider the transaction prices between wholesalers and providers in setting AWP, it did not report transactional prices to the compendia or Medi-Cal. As demonstrated above, this is simply untrue.

Mylan further disputes any implication or inference that it was obligated to report “its transactional prices” or “any average or compilation of these prices” as its AWP or that California expected Mylan’s AWP to reflect prices currently paid in the marketplace for Mylan’s drugs. California has never defined AWP as anything other than a price listed in a compendia. (Joint SOF at ¶ 20.) Moreover, California has understood since at least the late 1970s that compendia AWP do not reflect prices actually paid in the marketplace and, in particular, significantly overstate providers’ costs for generic drugs. (Joint SOF at ¶¶ 22-49.)

19. There was no fixed or predictable relationship between the AWP that Mylan reported to FDB and the prices at which its products were sold to the retail class of trade. (Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20; Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 37:6-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-139:18.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 19 and any implication or inference that the AWP that Mylan reported to FDB were required to bear a “fixed or predictable relationship” to the “prices at which its products were sold to the retail class of trade.” Mylan’s AWP is generally a price that is set at the time of launch in reference to the equivalent brand product’s AWP and any generic products’ AWP where available. (Palermo Decl., Ex. E at 67:2-22; Palermo Decl., Ex. F at 130:16-132:18; Palermo Decl., Ex. G at 138:8-140:21; Palermo Decl., Ex. H at 64:8-16.) However, the manner in which Mylan sets AWP varies from “product to product,” based on a number of factors. (Palermo Decl. Ex. H at 64:8-16, 92:16-93:4.) Mylan further states that it reports the AWP to various pricing compendia, such as First DataBank, in order to “get [Mylan’s] drug classified by First DataBank as a generic drug eligible for

substitution.” (Palermo Decl., Ex. E at 67:02-22; Palermo Decl., Ex. I at 17:20-18:2.) Mylan’s primary purpose for reporting AWP to the pricing compendia was “to make the marketplace aware that the products were being marketed and were available for sale.” (See Palermo Decl., Ex. I at 17:15-18:2.)

Mylan does not dispute that AWP is generally not the price at which Mylan *sells* its products to its own customers. However, as Mylan’s 30(b)(6) designee, Brian Roman, testified, Mylan’s products may be sold at AWP somewhere downstream:

- Q. Okay. Well, let’s establish one thing based on your last answer. You do agree with me, sir, that the term “average wholesale price” is not the price at which Mylan has ever sold any drugs to its customers?
- A. I can’t be categorical about it. We’ve been in business 45 years and we sell about 150 different drugs today. So I don’t know whether Mylan has sold products at AWP to its customers. It’s possible we have at some point. But as a general matter, AWP is not a price at which Mylan sells Mylan’s products to Mylan’s customers. It doesn’t mean it’s not a price at which our products are sold downstream. The pharmacy may charge AWP to its customer, for example.

(Palermo Decl., Ex. E at 50:06-19.)

Mylan objects to CA-Mylan-SOF ¶ 19 and any contention that Plaintiffs understood AWP to represent the average of actual prices paid by providers. California has never defined AWP as anything other than a price listed in a compendia. (Joint SOF at ¶ 20.) Moreover, California has understood since at least the late 1970s that compendia AWP’s do not reflect prices actually paid in the marketplace and, in particular, significantly overstate providers’ costs for generic drugs. (Joint SOF at ¶¶ 22-49.)

Moreover, California made its understanding of AWP clear to Mylan. On July 17, 2002, Mike Namba from Medi-Cal emailed Eric Belldina at Mylan to illustrate how Medi-

Cal calculated its net cost per unit for various types of drugs. (Palermo Decl., Ex. S; Palermo Decl., Ex. T.) One of the examples is the "Medi-Cal Net Price Cost Calculation" for "AWP-5% Generic drug." (Palermo Decl., Ex. S at CAAG/DHS-E0039868; Palermo Decl., Ex. T at CAAG/DHS-0068438.) The calculations show that, for a drug with AWP at \$3.00 not subject to a FUL or MAIC, Medi-Cal's lowest price per capsule is \$2.85 (AWP-5%). (Palermo Decl., Ex. S at CAAG/DHS-E0039868; Palermo Decl., Ex. T at CAAG/DHS-0068438.) The AMP, "as reported to HCFA," is \$0.50. (Palermo Decl., Ex. S at CAAG/DHS-E0039868; Palermo Decl., Ex. T at CAAG/DHS-0068438.) The illustration proceeds to determine Medi-Cal's Net Price, stating that "[i]n this example, Medi-Cal agrees to add a drug to the List if the manufacturer will guarantee that Medi-Cal's price will be \$2.00 per capsule. Since the AWP is inflated, the manufacturer must rebate a very large amount to reach the net price." (Palermo Decl., Ex. S at CAAG/DHS-E0039868; Palermo Decl., Ex. T at CAAG/DHS-0068438.) The difference between Medi-Cal's lowest price of \$2.85 and Medi-Cal's net price of \$2.00 is \$0.85, which represents the "total amount that must be rebated from [the] manufacturer to Medi-Cal." (Palermo Decl., Ex. S at CAAG/DHS-E0039868; Palermo Decl., Ex. T at CAAG/DHS-0068438.) At his deposition, Mr. Namba confirmed his understanding of AWP:

Q. .... Mr. Namba, if you could turn to the second page of that E-mail print-out, and I recognize it's a little tricky to read because of the way it -- it printed, but kind of -- just a little past what I think would be the middle of the page, if you see, there's a line that says "Medi-Cal's net price calculation," and it -- it walks through an example of \$2 per capsule. Do -- do you see that?

A. Yes.

Q. Okay. And it reads a little further down the page, "In this example Medi-Cal agrees to add a drug to the list if the manufacturer will guarantee that Medi-Cal's price will be \$2 per capsule. Since the AWP is inflated, the



manufacturer must rebate a very large amount to reach the net price." Is that right?

A. Yes.

Q. And so that was your understanding at the -- at the time you wrote this E-mail to the gentleman from Mylan in 2002, that for -- at least in this example, a large rebate would be required to -- to get -- to reach net price due to the inflation of AWP?

A. Correct.

(Palermo Decl., Ex. U (Namba) at 172:11-173:14.)

Mylan further disputes CA-Mylan-SOF ¶ 19 on the grounds that it mischaracterizes the testimony cited. Neither Brian Roman, Hal Korman nor Steve Krinke testified that there was no fixed or predictable relationship between Mylan's reported AWP's and the prices at which its products were sold. Mr. Roman testified that Mylan generally did not sell to its customers at AWP. Mr. Korman and Mr. Krinke both testified regarding the criteria they used in setting Mylan's AWP's, explaining that they did not consider actual wholesaler prices charged to pharmacies as Mylan is not privy to such data.

20. Mylan was aware of or on notice of Medicaid and Medi-Cal reimbursement policies in general. (Paul Ex. 12 (6/10/09 Brian Roman Dep.), at 133:22-135:11; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 63:16-65:12, 240:9-242:3, Ex. 12, Ex. 42; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 120:1-121:19, Ex. 10.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 20 to the extent it imposes or seeks to impose on Mylan, either retroactively or prospectively, an obligation to investigate the intricacies and rationale, written or unwritten, behind each state agency's Medicaid reimbursement policy and payments to pharmacies participating in the Medicaid program. At all relevant times, Mylan has complied with the legal requirements, standards or procedures that govern the manner in which

drug manufacturers interact with the various state Medicaid programs, including Medi-Cal, and takes its obligations seriously:

Q. Your company is responsible for knowing the rules and regulations of the Medicaid program; is that correct?

MR. ESCOBAR: Objection to the form of the question.

A. I -- I'd agree that we're responsible for knowing the rules and regulations that govern the way that we interact with the Medicaid program. There are a lot of aspects of the Medicaid program that we don't participate in, for example, when the Medicaid program pays doctors and things like that. There's -- there are things that we are involved in and many things that we're not. And we are -- we are certainly responsible for and take seriously our obligation to understand, know and comply with the rules that apply to us.

Q. And does your company assume the responsibility of behaving completely honestly and above board in connection with the states' Medicaid programs?

A. Absolutely.

Q. And your company is responsible for knowing the laws that govern the states' Medicaid programs; is that correct?

MR. ESCOBAR: Objection to the form.

A. Again, the rules that apply to the way that we interact with the Medicaid programs, I'd agree with that.

(Palermo Decl., Ex. A at 61:12-62:21.) The corporate compliance department at Mylan has ensured Mylan's compliance with the "[l]aws, regulations, ethics, ...[ Mylan's] own code of ethics, [and] standards for interactions with health care providers." (Palermo Decl., Ex. E at 134:1-4.)

Mylan's obligations, duties and responsibilities under the rebate program and Medicaid programs generally, are precisely delineated in Section II of the Medicaid rebate agreement, which includes, *inter alia*, an obligation to make timely rebate payments to each state

for drugs covered by Medicaid, calculate and report AMP on a quarterly basis for each NDC beginning with the first quarter of 1991, calculate and report any prior quarter adjustments to AMP, directly notify the states of a new drug's coverage, to retain records of underlying data used to calculate AMP for a specified period of time, and to comply with the conditions of 42 U.S.C. § 1396 and "changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer." (Palermo Decl., Ex. L § II.) Mylan Pharmaceuticals Inc. has fully complied with the terms and conditions set forth in its rebate agreement, as well any legal requirements, standards and procedures of the Medicaid program applicable to participating drug manufacturers. (Palermo Decl., Ex. G at 66:09-72:13; Palermo Decl., Ex. A at 61:12-62:07; Palermo Decl., Ex. E at 57:12-23, 81:15-82:5; Palermo Decl., Ex. H at 278:09-280:01; Palermo Decl., Ex. M at 157:07-158:12.) Neither the rebate agreement nor 42 U.S.C. § 1396 instruct drug manufacturers as to how AWP should be defined, calculated, or reported to third-party pricing compendia. (*See* Palermo Decl., Ex. L; 42 U.S.C. § 1396 *et seq.*)

Mylan also disputes the characterization implicit in the statement "aware of or on notice of Medicaid and Medi-Cal reimbursement policies." It is not Mylan's practice or policy to consider state Medicaid reimbursement formulas or payments when setting its prices. (Palermo Decl., Ex. G at 194:18-195:15.) Indeed, present and former employees of Mylan have consistently testified that it has not been Mylan's practice or policy to consider reimbursement payments to providers when setting or reporting AWP for its products. (Palermo Decl., Ex. I at 17:15-18:13; Palermo Decl., Ex. G at 181:03-22.) Nor is it Mylan's practice or policy to consider state Medicaid reimbursement formulas or payments when reporting AWP and WAC to pricing compendia. (Palermo Decl., Ex. I at 17:05-18:13.) It is not and has not been Mylan's

practice or policy to attempt to ensure or maximize Medicaid reimbursement payments to pharmacies when selling or marketing its products to customers. (Palermo Decl., Ex. E at 28:12-29:10; Palermo Decl., Ex. N at 238:13-239:03.) It is not Mylan's general practice or policy to monitor or track how each of the hundreds of different drugs manufactured and sold by Mylan were being reimbursed by various state Medicaid agencies. (Palermo Decl., Ex. N at 193:14-194:07; Palermo Decl., Ex. B at 142:02-08.) Moreover, Mylan has not received any part of the reimbursement amount paid by Medicaid. (*See* Palermo Decl., Ex. H at 272:9-15.)

It is not Mylan's practice or policy to attempt to "target a Medicaid market" when selling or marketing its products to customers:

Q. What I'm really asking is: Does Mylan make concerted efforts to market its drugs that are reimbursed by Medicaid and take any particular steps to promote or maintain that market?

MR. ESCOBAR: Objection to the form.

A. We don't think about a Medicaid market or target a Medicaid market or anything like that. What we do is try to sell our products to our customers at Mylan Pharmaceuticals. Those are principally drug wholesalers and these warehousing retail chains. And we sell based on the competitive environment that we're in where we're trying to get business, and there are other generic companies, often many other generic companies, competing to get that same business. So we're competing on price, and that would be our focus. We are looking for ways to make sure our customers can get our product, that it's not on back order, that we're able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive. So that's the focus of our sales and marketing, not the back end of reimbursement.

(Palermo Decl., Ex. E at 28:12-29:10.) As Mr. Krinke, director of trade relations and government affairs at Mylan Pharmaceuticals Inc. during the relevant time period, testified:

Q: Would you agree with me that a manufacturer trying to se[ll] pharmaceuticals to pharmacies, that maximizing the pharmacies' profitability on the product is a good way to try and sell the product?

MR. ESCOBAR: Objection to the form.

A. That's not Mylan's focus of selling products to our customers. As I mentioned, we don't know what kind of contracts they sign with third-party payers, so we just try to sell them the product at the price that they can live with and that we are happy with, and what happens after that is their responsibility.

(Palermo Decl., Ex. N at 238:13-239:03.) The primary focus of Mylan's sales and marketing efforts is not aimed "at the back end of reimbursement" but rather is designed to "make sure our customers can get our product, that it's not on back order, that we're able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive." (Palermo Decl., Ex. E at 28:12-29:10; *see also* Palermo Decl., Ex. O at TXMylan02893476.) Mr. Cunard, former VP of sales and marketing, testified:

Q. And what were the general basis (sic) on which you perceived that you competed with other companies with respect to the sale of pharmaceutical products?

A. As indicated earlier, price, supply, value-added services, CE programs

\* \* \*

A. Price, supply, value-added services such as continuing education programs, quality of product, reliability, reputation.

(Palermo Decl., Ex. H at 273:7-16.)

This is further corroborated by testimony of former sales personnel at Mylan Pharmaceuticals Inc., including Mr. Mauro, a national accounts manager during the relevant time period, who testified:

Q. Would you agree that part of your job as vice president for sales and as a director of the NAMs, the national account managers, and so forth over several years, part of your job was to try to convince customers how they can increase their profits when they buy and sell Mylan drugs?

MR. ESCOBAR: Objection to the form.

A. No, that was not something we did. The way we tried to promote our products to our customers were we were providing a broad offering of new items with a robust pipeline to keep them in service, and the company hasn't had a recall from a manufactured product in over 47 years.

(Palermo Decl., Ex. P at 278:4-18.) As Bob Potter, the Vice President of sales and marketing at Mylan Pharmaceuticals Inc. during the relevant time period, also stated:

Q. And reimbursement was never a concern in all those years when you were selling product to your customers?

A. It may have been a concern on their point, but our point is we go with our best price, and they make the decision if they'd like to buy our product or not. There's other products available in the hundreds of products that we do have.

I think if you go down to the key, also to influence sales, on this sheet, the most important ones that we haven't talked about is the value of our product, where we haven't had any recalls, and that is a very important piece of our whole [selling] process.

(Palermo Decl., Ex. Q at 77:12-78:3.)

21. Mylan was aware of or on notice that Medi-Cal reimbursed providers for pharmaceutical products based, in part, on the reported AWP of the products. (Paul Ex. 9 (10/30/08 Robert Cunard Dep.), at 196:20-197:6; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 241:3-15; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 153:22-155:16; Paul Ex. 12 (6/10/09 Brian Roman Dep.), at 141:19-143:11.)

**RESPONSE:**

Mylan disputes CA-Mylan-SOF ¶ 21. Although some Mylan employees may have had access to publicly available information relating to Medicaid reimbursement formulas,

when setting its prices, Mylan generally did not monitor or track how each of the hundreds of different drugs manufactured and sold by Mylan were being reimbursed by various state Medicaid agencies. (Palermo Decl., Ex. E at 29:22-30:10; Palermo Decl., Ex. N at 193:14-194:07; Palermo Decl., Ex. B at 142:02-08.) It was not Mylan's policy or general practice to monitor or track the various FULs that may apply to each of the hundreds of drugs manufactured and sold by Mylan and how that may impact pharmacy reimbursement. (Palermo Decl., Ex. G at 194:18-195:15 (Mylan "did not make a concerted or regular effort to keep track of the changing methodologies for Medicaid reimbursement"); Palermo Decl., Ex. N at 195:21-196:21 (testifying that "he could not see how Federal Upper Limit could limit reimbursement of Mylan's products" and that he "could not think of an occasion" when he had discussed FULs with anyone at Mylan); Palermo Decl., Ex. V at 218:10-16 ("I didn't know and – and don't know today what the – what the methodology is for setting FULs.").) As Robert Cunard, former VP of marketing at Mylan Pharmaceuticals Inc. further testified, the notion that there was a policy at Mylan to maximize reimbursement payments to pharmacies is "fundamentally flawed." (Palermo Decl., Ex. H at 119:08-120:03.)

It is Mylan's general understanding that state Medicaid agencies have flexibility in determining how they run their Medicaid programs, which includes designing and implementing their reimbursement payment methodology to ensure access to care and compliance with any other applicable federal statutes and regulations. (Palermo Decl., Ex. E at 30:12-31:03.) As Mylan's 30(b)(6) designee, Brian Roman, testified:

Q. Why don't we do this. Let's look briefly at Medicaid reimbursement and how it works. Do you have an understanding about how Medicaid reimbursement works?

A. Yeah. My understanding is that it differs from state to state. And with any state, it probably has changed over time. But what you will see is various -- each state designing their

own program the way they want to design it to pay -- find a way to pay pharmacies to make sure that the people in their state who are getting Medicaid benefits have access to the medicines that they need. And like I said, every state has their own way of going about doing that, of designing their program in a way that they feel is efficient. And that's my general understanding of it.

(Palermo Decl., Ex. E at 30:12-31:03.) Mylan does not have any involvement in how state Medicaid programs determine or apply their state Medicaid reimbursement formulas. (Palermo Decl., Ex. H at 125:14-126:17 (Mylan does not “control” or “influence” the “variables that would go into a reimbursement methodology”).) Throughout the relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the lower of EAC, the FUL, the MAIC, or the charge submitted by the provider. (Joint SOF at ¶ 18; Robben Decl., Ex. 13.) Based on this lower-of payment methodology and the usual and customary charge or billed amount, which generally represents in most states the usual and customary charge by the pharmacy for its services to the general public, Mylan lacks visibility into whether the AWP or WACs reported for its products, were in fact being used by California or other state Medicaid programs to calculate reimbursement payments to providers. (Palermo Decl., Ex. E at 171:22-23; Palermo Decl., Ex. H at 125:14-126:17.)

As stated above, present and former employees of Mylan have consistently testified that it has not been Mylan's practice or policy to consider reimbursement payments to providers when setting or reporting AWP for its products. (Palermo Decl., Ex. I at 17:15-18:13; Palermo Decl., Ex. E at 181:03-22.) Nor has it been Mylan's practice or policy to consider state Medicaid reimbursement formulas or payments when reporting AWP and WAC to pricing compendia. (Palermo Decl., Ex. I at 17:05-18:13.) It has not been Mylan's practice or policy to attempt to ensure or maximize Medicaid reimbursement payments to pharmacies when selling or



marketing its products to customers. (Palermo Decl., Ex. E at 28:12-29:10; Palermo Decl., Ex. N at 238:13-239:03.) It is not Mylan's general practice or policy to monitor or track how each of the hundreds of different drugs manufactured and sold by Mylan were being reimbursed by various state Medicaid agencies. (Palermo Decl., Ex. N at 193:14–194:07; Palermo Decl., Ex. B at 142:02-08.) Moreover, Mylan has not received any part of the reimbursement amount paid by Medicaid. (*See* Palermo Decl., Ex. H at 272:9-15.)

Indeed, the primary focus of Mylan's sales and marketing efforts is not aimed "at the back end of reimbursement" but rather is designed to "make sure our customers can get our product, that it's not on back order, that we're able to fill their orders, get it to them quickly, get them a high quality product at a price that is competitive." (Palermo Decl., Ex. E at 28:12-29:10; *see also* Palermo Decl., Ex. O at TXMylan02893476.) Mylan's primary purpose for reporting AWP to the pricing compendia was "to make the marketplace aware that the products were being marketed and were available for sale." (*See* Palermo Decl., Ex. I at 17:15-18:2.) As Mr. Cunard, former VP of sales and marketing testified:

Q. And what were the general basis (sic) on which you perceived that you competed with other companies with respect to the sale of pharmaceutical products?

A. As indicated earlier, price, supply, value-added services, CE programs

\* \* \*

A. Price, supply, value-added services such as continuing education programs, quality of product, reliability, reputation.

(Palermo Decl., Ex. H at 273:7-16.)

This is further corroborated by the testimony of former sales personnel at Mylan Pharmaceuticals Inc., including Mr. Mauro, a national accounts manager during the relevant time period, who testified:

Q. Would you agree that part of your job as vice president for sales and as a director of the NAMs, the national account managers, and so forth over several years, part of your job was to try to convince customers how they can increase their profits when they buy and sell Mylan drugs?

MR. ESCOBAR: Objection to the form.

A. No, that was not something we did. The way we tried to promote our products to our customers were we were providing a broad offering of new items with a robust pipeline to keep them in service, and the company hasn't had a recall from a manufactured product in over 47 years.

(Palermo Decl., Ex. P at 278:4-18.) As Bob Potter, the Vice President of sales and marketing at Mylan Pharmaceuticals Inc. during the relevant time period, also stated:

Q. And reimbursement was never a concern in all those years when you were selling product to your customers?

A. It may have been a concern on their point, but our point is we go with our best price, and they make the decision if they'd like to buy our product or not. There's other products available in the hundreds of products that we do have.

I think if you go down to the key, also to influence sales, on this sheet, the most important ones that we haven't talked about is the value of our product, where we haven't had any recalls, and that is a very important piece of our whole [selling] process.

(Palermo Decl., Ex. Q at 77:12-78:3.)

22. Plaintiffs' expert, Dr. Leitzinger, used data provided by Mylan to estimate the average prices paid by pharmaceutical wholesaler's customers [i.e., providers] for each of the 217 relevant Mylan NDCs. Dr. Leitzinger did that by calculating the prices that wholesalers paid to Mylan for each NDC and then applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each such NDC. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 4.)

His methodology is explained more fully at paragraphs 12-20 of his Report, which is attached as Ex. A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the “Industry Profile and Healthcare Factbook,” published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7 percent and 5.4 percent. (Paul Ex. 14 (Leitzinger Decl.), Ex. A at ¶ 20, n.20.)

**RESPONSE:**

For the purposes of this motion, Mylan does not dispute that Dr. Leitzinger’s report contains what Dr. Leitzinger purports to be average prices for the Subject Drugs, but Mylan disputes that California had an expectation that Mylan would calculate the AWP’s for its Subject Drugs in the manner described CA- Mylan -SOF ¶ 22, that there is any basis to contend that Mylan should have calculated its AWP’s in the manner described in CA- Mylan -SOF ¶ 22 or should have reported the figures listed in Dr. Leitzinger’s report as its AWP’s, or that Dr. Leitzinger’s calculations are otherwise probative evidence of any of the elements of California’s claims against Mylan. (Palermo Decl., Ex. W at ¶¶ 179-80.) Mylan further disputes any implication or inference that the purported “average prices paid” for the Subject Drugs retroactively derived by Dr. Leitzinger and the alleged methodology by which Dr. Leitzinger performed such derivations are in any way accurate, appropriate or material to this case.

Moreover, Plaintiffs’ citation to Paragraph 20 and note 20 of Dr. Leitzinger’s report is unavailing as they do not support the statements in CA-Mylan-SOF ¶ 22.

23. Ex. 4 to Dr. Leitzinger’s Report shows in column (6) the “spread” (the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the 217 relevant Mylan NDCs on a quarter-by-quarter basis from the first quarter of 1994 through the fourth quarter of 2004. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 5.)

**RESPONSE:**

For the purposes of this motion, Mylan does not dispute that Dr. Leitzinger’s report contains what Dr. Leitzinger purports to be the difference between AWP and “average net

quarterly prices” for the Subject Drugs, but Mylan disputes that Dr. Leitzinger’s calculations of these figures are probative evidence of any of the elements of California’s claims against Mylan, or are probative evidence of the measure of any purported injury suffered by California, if any, *inter alia*, because Dr. Leitzinger failed to take into account legitimate policy reasons California had for paying providers more than their actual acquisition cost for the Subject Drugs. (Palermo Decl., Ex. W at ¶¶ 43-44.) Mylan further disputes any implication or inference that the purported “average prices” “or “average net quarterly prices” for the Subject Drugs retroactively derived by Dr. Leitzinger and the alleged methodology by which Dr. Leitzinger performed such derivations are in any way accurate, appropriate or material to this case.

24. For over 93 percent of the Mylan NDC/quarter combinations for which he had complete data, the AWP reported by Mylan exceeded the average net quarterly prices paid by wholesalers’ customers by at least 100 percent. For 80 percent of those NDC/quarter combinations, the spread exceeded 300 percent, with some greater than 2,000 percent. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 6.)

**RESPONSE:**

For the purposes of this motion, Mylan does not dispute that Dr. Leitzinger’s report contains what Dr. Leitzinger purports to be the difference between AWP and “average net quarterly prices” for the Subject Drugs, but Mylan disputes that Dr. Leitzinger’s calculations of these “spreads” are probative evidence of any of the elements of California’s claims against Mylan, or are probative evidence of the measure of any purported injury suffered by California, if any, *inter alia*, because Dr. Leitzinger failed to take into account legitimate policy reasons California had for paying providers more than their actual acquisition cost for the Subject Drugs.. (Palermo Decl., Ex. W at ¶¶ 43-44.) Mylan further disputes any implication or inference that the purported “average prices” “or “average net quarterly prices” for the Subject Drugs retroactively derived by Dr. Leitzinger and the alleged methodology by which Dr. Leitzinger performed such derivations are in any way accurate, appropriate or material to this case.

25. For purposes of calculating the overpayments made by the State for the 217 relevant Mylan NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Mylan by at least 25 percent. For each remaining claim, he calculated the difference between the actual ingredient cost reimbursed by the State and an amount 25 percent above the average net price paid by wholesalers to Mylan. That difference was the overpayment he found. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 7.)

**RESPONSE:**

For the purposes of this motion, Mylan does not dispute that Dr. Leitzinger's report contains what Dr. Leitzinger purports to be the difference between AWP and "average net prices" for the Subject Drugs, but Mylan disputes that there is any basis to conclude that California only ever intended to reimburse providers at 25 percent above what wholesalers paid Mylan to acquire drugs, or that Dr. Leitzinger's calculations are otherwise probative evidence of any of the elements of California's claims against Mylan, or are probative evidence of the measure of any purported injury suffered by California, if any. Mylan further disputes that the existence of a difference between Medi-Cal's reimbursement payment for a drug and a providers' actual cost for a drug constitutes an "overpayment" because California deliberately adopted a reimbursement methodology that it knew would pay providers more than their actual acquisition costs for drugs to achieve its own policy goals. (Palermo Decl., Ex. W at ¶¶ 182-88.) Mylan further disputes any implication or inference that the purported "average prices" "or "average net quarterly prices" for the Subject Drugs retroactively derived by Dr. Leitzinger and the alleged methodology by which Dr. Leitzinger performed such derivations are in any way accurate, appropriate or material to this case.

26. Mylan has contended that its reported AWP's did not reasonably reflect providers' acquisition costs. (Paul Ex. 13 (Mylan's Objections and Responses to Plaintiff's First Set of Interrogatories), at Interrogatory Number 12, p. 25, "... AWP does not reflect providers' acquisition costs;" Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

**RESPONSE:**

Mylan disputes CA- Mylan -SOF ¶ 26 to the extent the evidence cited does not support Plaintiffs' statement and because Plaintiffs selectively and misleadingly quote from Mylan's Objections and Response to Plaintiffs' Interrogatory No. 12. As the rest of Mylan's response to Plaintiffs' Interrogatory No. 12 reads:

Mylan further states that, during the Subject Time Period, California and the federal government have been aware that AWP does not reflect providers' acquisition costs. California has received directives and/or reports from the federal government that AWP does not reflect the cost to providers for Mylan's drugs. For example, the Department of Health and Human Services Office of Inspector General Report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed under the Medicaid Prescription Drug Program of the California Department of Health Services," (A-06-95-00062), dated May 1996, stated that in California, AWP exceeded invoice prices by approximately 41.4 percent for generic drugs. Mylan refers California to a letter from John Rodriguez, Deputy Director of the California Department of Health Services, dated March 25, 1996, acknowledging the receipt of the draft OIG report (letter attached to said report at Appendix 4).

(Paul Ex. 13 at 25.)

Mylan further states that although AWP is generally not a price at which Mylan *sells* its drugs, it is possible that some of Mylan's products may be sold at AWP downstream.

(Palermo Decl., Ex. E at 49:23-50:19.)

Dated: December 21, 2009

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on December 21, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Christopher C. Palermo  
Christopher C. Palermo